K042949 1 of 1

C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

NOV - 9 2004

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	770-784-6451
Contact Person's Fax:	770-784-6419
Date of Preparation:	October 25, 2004

B. DEVICE NAME:

Trade Name:	PelviLace™ TO BioUrethral Support System
Common/Usual Name:	Suburethral Sling
Classification Names:	PAG – Mesh, Surgical, Polymeric

C. PREDICATE DEVICE NAME:

Trade Names: InnerLace™ BioUrethral Support System and Uretex™ TO Transobturator Urethral Support System

D. DEVICE DESCRIPTION:

The Bard® PelviLace™ TO BioUrethral Support System consists of the PelviLace Pelvicol implant and introducers. The introducers are used to place the implant which provides a natural backboard for the urethra during abdominal pressure increases.

E. INTENDED USE:

The PelviLace™ TO BioUrethral Support System is used for the treatment of stress urinary incontinence.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject PelviLace™ TO BioUrethral Support System has the same intended use, design and fundamental scientific technology as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. John C. Knorpp
Senior Regulatory Affairs Specialist
C.R. Bard, Inc., Urological Division
8195 Industrial Boulevard
COVINGTON GA 30014

SEP 28 2012

Re: K042949
Trade/Device Name: PelviLace™ Transobturator BioUrethral Support System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAG
Dated: October 25, 2004
Received: November 1, 2004

Dear Mr. Knorpp:

This letter corrects our substantially equivalent letter of November 9, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K042949

Device Name: PelviLace™ Transobturator BioUrethral Support System

Indications for Use:

The PelviLace™ Transobturator BioUrethral Support System is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for use as a pubourethral sling for the treatment of stress urinary incontinence in women resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042949

(Recommended Format 11/13/2003)